NDA 19-510/S-026
NDA 20-249/S-009

Merck Research Laboratories
Attention: Michelle W. Kloss, Ph.D.
P.O. Box 4, BLA-20
West Point, PA 19486-0004

MAR 18 1999

Dear Dr. Kloss:

Please refer to your supplemental new drug applications dated January 27, 1999, received January 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid (famotidine) Injection and Injection Premixed.

We acknowledge receipt of your correspondence dated February 5, 1999.

These supplements provide for the addition of the following contraindication statement to the end of the CONTRAINDICATIONS section of the package insert: "Cross sensitivity in this class of compounds has been observed. Therefore, PEPCID should not be administered to patients with a history of hypersensitivity to other H2-receptor antagonists."

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 27, 1999). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Michael Folkendt, Regulatory Project Manager, at (301) 827-1602

Sincerely,

3-19-99

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and